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| EXAMINER | |
|---|---|
| GIBBS, TERRA C | |

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| 1635 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/073,060 | MU ET AL. | |
| | Examiner | Art Unit | |
| | Terra C. Gibbs | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3,9,11,22,24,39,40,42,44,45,47,52,53,58-70,73,74 and 77-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,9,11,22,24,39,40,42,44,45,47,52,53,58-70,73,74 and 77-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This Office Action is a response to Applicant's Amendment filed July 23, 2007.

Claims 1, 9, 22, 52, 59, and 62 have been amended.

Claims 1, 3, 9, 11, 22, 24, 39, 40, 42, 44, 45, 47, 52, 53, 58-70, 73, 74, and 77-82 are pending in the instant application.

Claims 1, 3, 9, 11, 22, 24, 39, 40, 42, 44, 45, 47, 52, 53, 58-70, 73, 74, and 77-82 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claim Rejections - 35 USC § 112*

In the previous Office Action mailed January 12, 2007, all pending claims were rejected under 35 U.S.C. 112, first paragraph for lack of enablement because the claims did not exclude *in vivo* applicability for enablement purposes. **This rejection is withdrawn** in view of Applicant's Amendment filed July 23, 2007. Specifically, the Examiner is withdrawing this rejection in view of Applicants Amendment to the claims to remove the term "biological" and recite that the sample is "isolated from" rather than "obtained from" to clarify that the methods are performed *ex vivo*.

In the previous Office Action mailed January 12, 2007, all pending claims were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. **This rejection is withdrawn** in view of Applicant's Amendment filed July 23, 2007. Specifically, the Examiner is withdrawing this rejection in view of Applicants Amendment to the claims to remove the term "biological" and recite that the sample is "isolated from" rather than "obtained from" to clarify that the methods are performed *ex vivo*.

***Withdrawal of Finality***

Applicants received a Final Office Action mailed January 12, 2007. After careful reconsideration of the pending claims of record, the Examiner has decided to withdraw the finality of the Office Action mailed January 12, 2007 in view of the new rejections presented below:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 39, 44, 52, 53, 58-61, 63, 65, 67, 68, and 77-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 39, 44, 52, 53, 58-61, 65, 67, 68, and 77-80 are indefinite because while the preamble of claims 1, 52, and 59 recites, "a method for diagnosing", the methods steps conclude with a comparison of gene copy number that "indicates the presence of a precancerous lesion or a cancer". There is not a clear nexus between the

purpose of the claim as stated in the preamble and the last method step. Thus, it is unclear how the method steps accomplish the purpose of the claim as stated in the preamble.

Claims 60 and 63 are unclear over the recitation, "RT-PCR" in reference to a method for determining gene copy number. RT-PCR is typically used to determine a level of mRNA expression, and RT-PCR is not used to determine a copy number of DNA, as a reverse transcription step is not required. Thus it is unclear how the use of RT-PCR is required to determine hepsin gene copy number.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 9, 11, 22, 24, 39, 40, 42, 44, 45, 47, 52, 53, 58-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a method for diagnosing an ovarian cancer in a mammal, comprising detecting and measuring the hepsin gene copy number in a sample of tissue isolated from a mammal that is suspected to be precancerous or

cancerous and comparing the gene copy number to a control gene copy number, wherein a detectable increase in amplification of the gene in the sample relative to the control indicates the presence of a precancerous lesion or cancer. The claims are also drawn to a method for monitoring the efficacy of a therapeutic treatment regimen in a patient comprising measuring the hepsin gene copy number in a first sample of a precancerous ovarian cell isolated from a patient at a first time point in the treatment regimen, measuring the hepsin gene copy number in a sample of precancerous cell isolated from the patient at a second time point in the treatment regimen, and comparing the gene copy number in the first and second samples, wherein data showing a detectable decrease in the gene copy number from the second sample relative to the first sample indicates that the treatment regiment is effective in the patient. The claims are also drawn to a method for monitoring the efficacy of a therapeutic treatment regimen in a patient comprising measuring hepsin mRNA or hepsin protein in a first sample of a precancerous ovarian, prostate, or lung cell isolated from a patient at a first time point in the treatment regimen, measuring the hepsin mRNA or protein in a sample of precancerous cell isolated from the patient at a second time point in the treatment regimen, and comparing the mRNA or protein in the first and second samples, wherein data showing a detectable decrease in the mRNA or protein from the second sample relative to the first sample indicates that the treatment regiment is effective in the patient.

The specification defines hepsin as including polymorphic variants, alleles, mutants and interspecies homologs that have substantial nucleotide homology with the

nucleotide sequence as set forth in SEQ ID NO:1 (see page 21, lines 12-19). This encompasses the hepsin subfamily of genes. Also, it is noted that the rejected claims do not recite any sequence identifier relating to hepsin. This sequence is thus considered to be defined by its function (i.e. the activity of hepsin) rather than by any one specific structure. Accordingly, the claims embrace methods of detecting and measuring hepsin, or any such molecule with analogous hepsin activity, known or yet to be discovered, along with any isoform or allele present within this species, or any variant, polymorphic or otherwise, that is within reasonable similarity from these families of proteins that retain hepsin activity.

The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

The Federal Circuit has recently clarified that a molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an

invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

Thus, the instant specification may provide an adequate written description of polypeptide antagonists, per Lilly by structurally describing a representative number of polypeptide antagonists that function as claimed or by describing structural features common to the members of the genus, which features constitute a substantial portion of the genus. Alternatively, per Enzo, the specification can show that the claimed invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

In this case, the specification does not describe the genus of the hepsin subfamily members that satisfies either the Lilly or Enzo standards. There are insufficient structural features common to all members of the genus of hepsin subfamily members. The only hepsin subfamily member specifically described in the specification associated with cancer or tumor samples is the hepsin gene identified by SEQ ID NO:1. One species of hepsin subfamily does not sufficiently describe the genus of the hepsin subfamily and does not meet the standard set forth in Lilly.

The instant specification may also provide an adequate written description of the genus of the hepsin subfamily if the specification can show that the claimed invention is

complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. The specification discloses only one species of the hepsin subfamily, the hepsin gene identified by SEQ ID NO:1. Thus, the specification does not describe sufficient structural characteristics that correlate with the ability of the genus of the hepsin subfamily to function as contemplated by the specification and for the reasons set forth above do not meet the standards set forth by Enzo.

Thus, the specification does not provide an adequate written description of the genus of the hepsin gene subfamily in claims 1; 3, 9, 11, 22, 24, 39, 40, 42, 44, 45, 47, 52, 53, 58-66 that is required to practice the claimed invention.

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Claims 1, 3, 9, 11, 22, 24, 39, 40, 42, 44, 45, 47, 52, 53, 58-70, 73, 74, and 77-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics.*, 8

USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

Nature of the invention and breadth of the claims

The invention is a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The claims are drawn to a method for diagnosing an ovarian cancer in a mammal, comprising detecting and measuring the hepsin gene copy number in a sample of tissue isolated from a mammal that is suspected to be precancerous or cancerous and comparing the gene copy number to a control gene copy number, wherein a detectable increase in amplification of the gene in the sample relative to the control indicates the presence of a precancerous lesion or cancer. The claims are also drawn to a method for monitoring the efficacy of a therapeutic treatment regimen in a patient comprising measuring the hepsin gene copy number in a first sample of a precancerous ovarian cell isolated from a patient at a first time point in the treatment regimen, measuring the hepsin gene copy number in a sample of precancerous cell isolated from the patient at a second time point in the treatment regimen, and comparing the gene copy number in the first and second samples, wherein data showing a detectable decrease in the gene copy number from the second sample

relative to the first sample indicates that the treatment regiment is effective in the patient. The claims are also drawn to a method for monitoring the efficacy of a therapeutic treatment regimen in a patient comprising measuring hepsin mRNA or hepsin protein in a first sample of a precancerous ovarian, prostate, or lung cell isolated from a patient at a first time point in the treatment regimen, measuring the hepsin mRNA or protein in a sample of precancerous cell isolated from the patient at a second time point in the treatment regimen, and comparing the mRNA or protein in the first and second samples, wherein data showing a detectable decrease in the mRNA or protein from the second sample relative to the first sample indicates that the treatment regiment is effective in the patient.

The claims broadly encompass detecting any measure of hepsin gene amplification in a test sample as compared to any control gene copy number.

Direction provided by the specification and working example

The instant specification teaches an example of the analysis of hepsin gene amplification in lung, ovarian, prostate, and breast tumors (see Table 2 and Table 4 and Example 1). The examples of the specification compare the gene copy number, as determined using a TaqMan 7700 Sequence Detector, in genomic DNA isolated from tumor samples versus a reference probe representing "a normal non-amplified, single copy region in the genome" (see last paragraph bridging pages 64 and 65). The data are summarized in Table 4 of the specification, which teaches that amplification was found in 5 out of 29 ovarian tumor samples, 1 out of 33 lung tumor samples, 2 of 35 breast tumor samples, and 0 out of 16 prostate tumor samples.

First, it is unclear what copy number in a tumor sample is required to be considered "amplified". While the definition of the term 'amplification' (pages 15 and 16 of the specification) provides that amplification of the hepsin gene resulting in a copy number greater than or equal to 2.5 is deemed to have been amplified, the definition continues to state that an increase in hepsin gene copy number less than 2.5 fold can still be considered amplification of the gene. In this case it is relevant to point out that, for a gene present as two copies such as hepsin, amplification resulting in a copy number of 2.5 is not the same as a 2.5 fold amplification (the later of which would result in a gene copy number of 5).

Second, the specification teaches only the analysis of tumor tissue samples, and does not provide any analysis indicating gene amplification in a precancerous lesion.

Third, the specification does not teach any example of the analysis of hepsin gene copy number in any non-tumor tissue sample. The specification does not teach, for example, if in non-tumor ovarian or breast samples from subjects matched in age and sex with an experimental sample population, one might find hepsin gene amplification.

The specification teaches only the analysis of hepsin gene copy number in various samples of primary tumor tissues. The specification does not teach the analysis of gene copy number in a biological subject from any non-tumor region, as is encompassed by the claims.

State of the art, level of skill in the art, and level of unpredictability

While the state of the art and level of skill in the art with regard to the determination of gene copy number in any particular sample is high, the level of unpredictability in associating gene copy number with a particular phenotype is even higher.

The unpredictability in using the invention as claimed is indicated by the data presented in the instant specification. For example, while the claims encompass a method for diagnosing an ovarian cancer, the data (Table 4) indicates identifying hepsin gene amplification in 5 out of 29 ovarian tumor samples. The data presented is void of any values proving statistical significance, and provide no explanations as to how much amplification is seen as significant in comparison to a control. Similarly, the claims encompass a method for monitoring the efficacy of a therapeutic treatment regimen in a patient. While the specification identifies hepsin gene amplification in 1 out of 33 lung cancers and 2 out of 35 breast cancers, this data is void of any values proving statistical significance. The prior art of Thisted (1998) provides guidance as to what is required to indicate that an association is statistically significant. Thisted teaches that it has become scientific convention to say that a P-value of 0.05 is considered significant (see page 5 - What does it mean to be 'statistically significant'), and that values above the conventional reference point of 0.05 would not be considered strong enough for the basis of a conclusion.

Additionally, it is unpredictable as to whether or not the data presented in Table 4 indicate that detection of hepsin gene amplification provides a reliable method of

diagnosing an ovarian cancer. Given the data from Table 4, it is unpredictable if a method with a false negative rate of 83% (24 of 29 not detected) in ovarian tumors, provides a reliable method for diagnosing an ovarian cancer. Similarly, it is unpredictable as to whether or not the data presented in Table 4 indicate that detection of hepsin gene amplification provides a reliable method for monitoring the efficacy of a therapeutic treatment regimen in a patient. Given the data from Table 4, it is unpredictable if a method with a false negative rate of 83% (24 of 29 not detected) in ovarian tumors, 97% (32 of 33 not detected) in lung tumors, and 94% (33 of 35 not detected) in breast tumors provides a reliable method for monitoring the efficacy of a therapeutic treatment regimen in a patient. The unpredictability is maintained with the lack of data regarding hepsin gene amplification in any non-tumor samples. For example, the prior art of Kandel et al (2001) teaches an analysis of amplification of the cyclin D1 gene amplification in breast cancer. The reference teaches that, taking into account the lack of amplification in some cases, and the presence of amplification in some controls (Table 2), there is not a significant association between gene amplification and risk of breast cancer (p.43 – Abstract; p.49 – left col., lns.16-18). It is thus unpredictable as to how one might use a determination of any level of hepsin gene amplification in a method for diagnosing an ovarian cancer or a method for monitoring the efficacy of a therapeutic treatment regimen in a patient.

The prior art does resolve the inadequacies of the data presented in the instant specification. The prior art teaches much unpredictability regarding the role of hepsin in biological processes and gene association studies in general. The post filing art

provides an example of this state of the art: Lucentini (2004) teaches that it is strikingly common for follow-up studies to find gene-disease associations wrong (left column, 3rd paragraph). Lucentini teaches that two recent studies found that typically when a finding is first published linking a given gene to a disease there is only roughly a one-third chance that the study will reliably confirm the finding (left column, 3rd paragraph). Lucentini teaches that bigger sample sizes and more family-based studies, along with revising statistical methods, should be included in the gene association studies (middle column, 1st complete paragraph). More specifically, the post filing art further corroborates the unpredictability present regarding the role of hepsin in a paper very recently published (September 1, 2007, by Wu et al.) teaching that "The physiological function of hepsin remains unknown" (see Abstract). The paper goes on to teach that, "In renal cell carcinomas, Zacharaski et al. reported strong hepsin staining on tumor cell membrane in all seven cases examined... However, two groups reported different results". The paper also teaches, "Clearly, additional studies with more patient samples are needed to better understand hepsin expression in renal cell carcinomas and its relationship with disease prognosis" (see page 5055, second column, first full paragraph). Additionally, the paper teaches, "The evidence of hepsin up-regulation in prostate cancer is striking but the biological significance remains unclear" (see page 5055, second column, second full paragraph). As such, the state of the art provides further unpredictability regarding the reliable practice of gene-association studies and specifically the hepsin gene.

Reasonable correlation must exist between the scope of the claims and the scope of enablement set forth, and it cannot be reasonably predicted that a method for diagnosing breast cancer in a mammal will predictably function as disclosed. Similarly, it cannot be reasonably predicted that a method for monitoring the efficacy of a therapeutic treatment regimen in a patient will predictably function as disclosed. Therefore, in view of the lack of predictability of the art, the breadth of the claims, the lack of guidance and support in the specification, and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as broadly claimed. Therefore, based on the evidence of record, and in light of these teachings, the skilled artisan would be forced to practice undue and unpredictable trial and error experimentation when practicing the instant invention.

Quantity of experimentation required

In order to practiced the methods as claimed, one would have to perform case: control experimentation in an effort determine that any level of hepsin gene amplification (as compared to any control gene copy number) is in fact indicative of a ovarian, prostate, or lung precancerous lesion or cancer in a statistically significant fashion. Even if such experimentation were to be performed, one might in fact find that there is no significant association between hepsin gene amplification and cancer.

Conclusion

Taking into consideration the factors outlined above, including the nature of the invention and the breadth of the claims, the state of the art, the level of skill in the art and its high level of unpredictability, the amount of guidance by the applicant and the

specific working examples, it is the conclusion the an undue amount of experimentation would be required to make and use the claimed invention.

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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tcg
August 29, 2007

/Sean McGarry/
Primary Examiner
AU 1635